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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/055,143	01/22/2002	John Chapman	18242-508 CIP2 (VI-8 CIP2	1572

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EXAMINER	
WINKLER, ULRIKE	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 09/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/055,143	CHAPMAN ET AL.	
	Examiner	Art Unit	
	Ulrike Winkler	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *6-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 13-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/02; 11/02; 7/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election of Group I (claims 1-5 and 13-20) in the reply filed on July 15, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449 received on April 8, 2002, April 9, 2002, November 8, 2002, and July 15, 2004 are attached to the instant Office Action.

Claim Rejections - 35 USC § 102

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Meryman et al. (WO 91/04659).

The instant invention is drawn to reducing the amount of an analyte found in mammalian blood the specification defines analyte to include proteins (cytokine, immunoglobulins), small molecules, bacteria, viruses or protozoa. Removal of the extracellular fluid from a red blood cell suspension results in a reduction of an analyte present in the extracellular fluid (a.k.a. serum).

Meryman et al. discloses the desirability to extend the shelf-life of refrigerated red-cells beyond the current 42 days (see page 5, lines 24-26). The reference discloses the collection of whole blood from a donor which is then centrifuged and resuspended in washing solution, the residual plasma concentration (which carries serum proteins, IgG cytokines and other analytes) is reduced by a factor of 10^2 or 10^3 (see examples 1-5). The preferred embodiment is to pack the

red blood cells by centrifugation and separating the red cells from the blood components and resuspending the red cells (see page 25, lines 19-30). The cells that have been stored in solution comprising dextrose, adenenine, manitol, sodium chloride (see table 1) for 42 days can acquire an additional 5 weeks of shelf life by washing the cells and resuspending with a solution containing glucose, sodium citrate, sodium phosphate and adeneine (see table 2 and page 25, lines 13-18). The reference discloses the washing and storage of red cells which includes the removal of blood components and extracellular fluid from the collected whole blood. Because removal of the extracellular fluid from blood removes an analyte found in the serum the instant invention is anticipated by Meryman et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 1-5 and 13-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maryman et al. (WO 91/04659) and Edson et al. (WO 00/18969).

The instant invention is drawn to reducing the amount of analyte found in a mammalian blood cell suspension using a process of washing the cell suspension which involves centrifugation and resuspension of the pelleted cell fraction. The blood cells retain viability after storage at 4C for 28 days, or 35 days. Removal of the extracellular fluid (1-5) results in a reduction of an analyte present in the extracellular fluid (a.k.a. serum). The method of washing reduces the level of extracellular protein (serum albumin, IgG, cytokine) in the blood cells suspension.

Meryman et al. teaches the desirability to extend the shelf-life of refrigerated red-cells beyond the current 42 days (see page 5, lines 24-26). The reference discloses the collection of whole blood from a donor which is then centrifuged and resuspended in washing solution, the residual plasma concentration (which carries serum proteins, IgG cytokines and other analytes) is reduced by a factor of 10^2 or 10^3 (see examples 1-5). The preferred embodiment is to pack the red blood cells by centrifugation and separating the red cells from the blood components and reuspending the red cells (see page 25, lines 19-30). The cells that have been stored in solution comprising dextrose, adenenine, manitol, sodium chloride (see table 1) for 42 days can acquire an additional 5 weeks of shelf life by washing the cells and resuspending with a solution containing glucose, sodium citrate, sodium phosphate and adeneine (see table 2 and page 25, lines 13-18). The reference teaches the washing and storage of red cells which includes the removal of blood components and extracellular fluid from the collected whole blood. The reference does not teach adding an analyte or therapeutic agent to the whole blood cell mix.

Edson et al. teach separating red blood cell from other blood components such as lymphocytes, neutrophils and platelets as wells as clotting factors and complement. The separation of the red blood cells can be achieved through centrifugation or through automated filtration systems (closed systems) (see page 14, lines 5-22). Blood cells are treated with a small molecule analyte (Pen102) which is an ethyleinmine oligomer inactivating agent. The treated cells are then washed by centrifugation to remove the analyte and removal of the analyte is monitored using HPLC procedures (see page 24-25). Washing the treated cells reduces the amount of analyte present in the cell suspension (see figure 5) each additional wash results in a further reduction in the analyte. The reference does not teach adding a wash solution that allows for prolonged storage at 4C.

It would have been obvious to one of ordinary skill in the art to use the washing and storage procedure as taught by Maryman et al. and apply it to the inactivation procedure as taught by Edson et al. Each of the references is interested in producing a transfusion blood product that can be used in a patient, by using washing steps that allow for prolonged storage of a blood cell component the treated blood as taught by Edson et al. would have greater applicability in the clinical setting as the process steps can be preformed and analyzed before the treated product is used on a patient. Optimizing experimental conditions, including starting volume and repeating the washing steps, falls within the skills of an ordinary artisan. If the timing of adding the modulating compound produces an unexpected result, applicant needs to point out what the unexpected results are. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions

of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) and *In re Huang,* 40 USPQ2d 1685 (CAFC 1996) (see paragraph spanning page 1688-1689). The references teach the washing and storage of red cells that includes the removal of blood components and extracellular fluid from the collected whole blood. The use of centrifugation and washing to remove extracellular components from the red blood cell pack is not novel, Applicants contribution over the prior art merely addresses that the washing steps are repeated to achieve a further reduction in the extracellular fluid component. The ordinary artisan would recognize that by adding additional washing steps to the methods disclosed in the prior art would reduce the amount of the extracellular fluid found in the original whole blood sample. Applicants have not provided any evidence that their procedure produces an unexpected result. Therefore, the instant invention is obvious over Maryman et al. (WO 91/04659) and Edson et al. (WO 00/18969).

Conclusion

No claims allowed.

Papers related this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989). The Group 1600 Official Fax number is: (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center representative whose telephone number is (571)-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 571-272-0912. The examiner can normally be reached M-F, 8:30 am - 5 pm. The examiner can also be reached via email [ulrike.winkler@uspto.gov].

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 571-272-0902.

ULRIKE WINKLER, PH.D.
PRIMARY EXAMINER 9/1/04